Hansa Medical

- PRESS RELEASE -
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First patient treated in Hansa Medical's Highdes-study

Hansa Medical AB (publ) today announced that the first patient has been treated and subsequently transplanted in the pivotal multicenter study Highdes using IdeS to desensitize highly sensitized patients prior to kidney transplantation.

The Phase II study will include approximately 20 highly sensitized patients awaiting kidney transplantation. Patients included in this new study have either failed on previous attempts of desensitization or the currently available methods are considered insufficiently effective.

The study is entitled *"A Phase II Study to Evaluate the Efficacy of IdeS (IgG endopeptidase) to Desensitize Transplant Patients with a Positive Crossmatch Test"* with the short name Highdes. The primary objective of the study is to assess the efficacy of IdeS in creating a negative crossmatch test in highly sensitized patients with a positive crossmatch test to their available donor. Converting the crossmatch test will enable transplantation in patients who would otherwise not qualify for transplantation.

The study will also evaluate safety, kidney function and immunogenicity during the 6-month follow-up period. The aim is to complete recruitment of approximately 20 patients over a 12-month period.

"We are very pleased that the first patient has been treated in our Hansa Medical-sponsored study with IdeS in the US. The study will recruit patients with an urgent need for kidney transplantation. Several of the patients have been on the waiting list for many years", commented Göran Arvidson, President and CEO of Hansa Medical AB.

It is expected that the study will provide pivotal data for filing a Biologics License Application, i.e. an application to the US Food and Drug Administration (FDA) for authorization to commercialize IdeS in the US. Three US sites will recruit patients to the Highdes study: Cedars-Sinai Medical Center in Los Angeles, The Johns Hopkins Hospital in Baltimore and New York University School of Medicine in New York. Hansa Medical is planning to add European sites to the study in order to support the regulatory process at the European Medicines Agency, EMA, for marketing authorization of IdeS in the European market.

More information about this study in refractory highly sensitized patients is available at www.clinicaltrials.gov under the identifier NCT02790437.

The information in this press release is disclosed pursuant to the EU Market Abuse Regulation. The information was released for public disclosure through the agency of the contact person stated below on October 3, 2016 at 08.30 CET.

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About highly sensitized patients

Approximately one third of the kidney patients in dialysis are sensitized to human leukocyte antigens (HLA). The presence of antibodies that react with a potential donor organ and create a positive crossmatch test is a significant barrier to transplantation due to the risk of acute antibody mediated rejection. Sensitized patients in general have an increased waiting time for transplantation. Depending on the level of HLA-immunization, some sensitized patients can be transplanted with treatment procedures using for example plasmapheresis or intravenous gamma globulin at specialized clinics. Patients included in the Highdes study will have failed on previous attempts of desensitization or will not be eligible for desensitization using currently available methods due to the strength and breadth of their HLA antibodies. These patients have one of the highest unmet medical needs in transplantation today.

About IdeS

IdeS, a unique molecule with a novel mechanism, is an enzyme that specifically cleaves human IgG antibodies. IdeS has been evaluated in a Phase I study in healthy subjects and in a Phase II study in sensitized patients awaiting kidney transplantation demonstrating that IdeS is highly effective in reducing anti-HLA antibodies to levels acceptable for transplantation with a favorable safety profile. In addition to the pivotal Highdes study, the efficacy and safety of IdeS in transplantation are currently investigated in two on-going Phase II studies in sensitized kidney patients in Sweden and the US. The Swedish study will be completed in Q4 2016 and the U.S. study is estimated to be completed during H1 2017. In addition to transplantation, IdeS has potential applications in a variety of rare autoimmune diseases.

About Hansa Medical AB

Hansa Medical is a biopharmaceutical company focusing on novel immunomodulatory enzymes. The lead project IdeS is an antibody-degrading enzyme in clinical development, with potential use in transplantation and rare autoimmune diseases. Additional projects focus on development of new antibody modulating enzymes, as well as HBP, a diagnostic biomarker for prediction of severe sepsis at emergency departments that is already introduced on the market. The company is based in Lund, Sweden. Hansa Medical's share (ticker: HMED) is listed on Nasdaq Stockholm.